

REMARKS

The Office Action dated March 11, 2004 presents the examination of claims 1-3 and 6-12. Claim 3 is canceled. Claims 1-2 and 7-12 are amended. Support for amendments to the claims is found in the specification, such as on page 2, lines 20-24. No new matter is inserted into the application.

Interview

An interview was held with the Examiner at the United States Patent and Trademark Office on October 25, 2004. The Examiner's cooperation in advancing prosecution of the present application is greatly appreciated.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner maintains the rejection of claims 2-3 and 7-9 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter neither described in, nor enabled by, the specification. Claim 3 is canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Written Description

Specifically, the Examiner asserts that claim 2 does not meet the requirements for written description because "a representative number of sequences that would have not less than 95% sequence identity to SEQ ID NO: 1" are not disclosed in the specification.

Applicants respectfully disagree and submit that the specification provides sufficient information to conclude that Applicants were in possession of the genus of nucleic acids recited in claim 2. Claim 2 is written in terms consistent with claims deemed supported by adequate written description in the "Revised Interim Written Description Guidelines Training Materials" (hereinafter "the Training Materials") published by the United States Patent and Trademark Office on January 5, 2001. Specifically, Example 14 of the Training Materials addresses claims that recite the invention in terms of percent identity to a reference sequence. Thus, Example 14 is relevant to the instant claim 2.

The claim in Example 14 states:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A → B.

This claim language is identical in its general content to that of claim 2 in that both a reference sequence and a biological

activity is set forth. Specifically, in claim 2, the reference sequence is SEQ ID NO:1 and the biological activity is promotion of expression of a polynucleotide encoding a protein of interest located downstream thereof. Furthermore, the disclosure in the instant specification is also almost identical to that in Example 14. There is a single species disclosed having the biological activity recited in the claims, and there is actual reduction to practice of a single disclosed species (i.e., SEQ ID NO: 1).

As noted in the analysis of Example 14, variants of a sequence having 95% identity thereto include variants having substitutions, deletions, insertions and additions; but all variants must possess the specified biological activity and must have 95% identity to the specified sequence. In the instant case, the specification indicates that the genus of nucleic acids that are variants of SEQ ID NO:1 does not have substantial variation since all of the variants must possess a specific biological activity and must have at least 95% identity to the reference sequence, SEQ ID NO:1.

Further, the specification describes structural attributes that are common to the members of the nucleic acid genus and that distinguish the nucleic acid genus. For example, the specification describes that the nucleic acid genus has the structural attribute of comprising a nucleotide sequence obtainable from a polynucleotide, wherein said polynucleotide is amplifiable from a

known rice genomic clone (SEQ ID NO: 5 of WO95/0934) with a combination of PCR primers selected from SEQ ID NOs: 4 and 6.

As also noted in the analysis of Example 14, the procedures for making variants of a sequence having 95% identity thereto which retain their biological activity are conventional in the art. In the instant case, the specification also provides a screening method, i.e., Example 1, which allows the skilled artisan to test for promoter activity by measuring GUS activity of transformed maize leaves by the method of Sheen (*Plant Cell*, 3:225-245, 1991). Thus, any potential nucleic acid that falls within the scope of, for example, claim 2 can be readily assayed.

In summary, the instant specification meets the requirements of 35 U.S.C. § 112 first paragraph as providing adequate written description (1) because the disclosure of a single species (i.e., SEQ ID NO:1) is representative of a genus because all members thereof must have at least 95% structural identity with the reference compound, and (2) because of the presence of an assay which Applicant provided for identifying all of the at least 95% identical variants which have the specified activity. As noted in Example 14, one of skill in the art would conclude that Applicant was in possession of the necessary common attributes possessed by members of the genus. Accordingly, for all of the reasons

discussed above, claim 2 fully complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

Enablement

The specification describes how to obtain potential nucleic acids or variants of the SEQ ID NO: 1 that are encompassed within the scope of claim 2. In other words, the specification discloses that variants having not less than 95% sequence identity to SEQ ID NO:1 can be obtained by substituting, deleting, or inserting one or more nucleotides of SEQ ID NO:1. Modification of nucleotide sequences is well known in the art. Further, the specification has provided an assay that allows one of skill in the art to readily determine which nucleotide sequences have promoter activity (see Example 1). Thus the full scope of the claimed invention can be practiced without undue experimentation.

Applicants respectfully submit that the instant claims recite subject matter that is fully enabled by, and described in, the specification, such that the requirements of 35 U.S.C. § 112, first paragraph are met. Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1, 3, and 7-12 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claim 3 is canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The Examiner maintains his assertion that "structural gene" is indefinite. In order to overcome this rejection, the recitation of "structural gene" is replaced with "polynucleotide encoding a protein of interest" as suggested by the Examiner. Further, the claims are amended to clarify that the promoter is operably linked to the polynucleotide.

In the last paragraph of page 4 of the Office Action, the Examiner rejects claims 1, 3, and 7-9 for lacking a comparative basis for the term "increases" or "increased." In order to overcome this rejection, the term "promotes" is used as agreed upon during the interview.

Applicants respectfully submit that the instant claims particularly point out and distinctly claim the subject matter which is the present invention, such that the requirements of 35 U.S.C. § 112, second paragraph are satisfied. Withdrawal of the instant rejection is therefore respectfully requested.

Rejections under 35 U.S.C. § 102(b)

The Examiner maintains the rejection of claims 3, and 7-9 under 35 U.S.C. § 102(b) for allegedly being anticipated by Ueki et al. (*Plant Cell and Physiology*, 40(6):618-623, 1999). Claim 3 is canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested. Claims 7 and 9 are amended to no longer depend on canceled claim 3. Thus, the instant rejection is overcome.

Rejection under 35 U.S.C. § 103(a)

The Examiner also rejects claims 3, 7-9, and 12 under 35 U.S.C. § 103(a) for allegedly being anticipated by Ueki et al. in view of Tanaka et al. (*Nucleic Acids Research*, 18(23):6767-6770, 1990). Claim 3 is canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested. Claims 7 and 9 are amended to no longer depend on canceled claim 3. Claim 12 depends from claim 7. Thus, the instant rejection is overcome.

Conclusion

Applicants respectfully submit that the above amendments and/or remarks fully address and/or render moot the rejections of record. The present application is in condition for allowance. The Examiner is respectfully requested to issue a Notice of Allowance indicating that claims 1-2 and 6-12 are allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of one (1) month to November 11, 2004, in which to file a reply to the Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

Appl. No. 09/856,725

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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